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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,120	12/14/2000	Francine Joly	GEI-082	2156
7590	08/06/2004		EXAMINER	
Charles A Muserlian Bierman Muserlian and Lucas 600 Third Avenue New York, NY 10016			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/700,120	JOLY ET AL.
	Examiner	Art Unit
	Blessing M. Fubara	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 July 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 57 and 58 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

Examiner acknowledges receipt of letter filed 07/27/04 in response to Examiner's inquiry regarding pending claims 57 and 58 and the recitation of algae extract, bacterial extract ...and phytoplankton extract as basic amino acids. Examiner also acknowledges receipt of applicants' request for reconsideration filed 07/16/04 in response to the final rejection of 04/20/04. No amendment to the pending claims was presented. Claims 57 and 58 remain pending.

1. The finality of the last office action is withdrawn because claims 57 and 58 have matters under 35 U.S.C. 112, second paragraph that are addressed below.

### ***Claim Rejections - 35 USC § 112***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57 and 58 recite selecting basic amino acids "from the group consisting of arginine...algae extract, bacterial extracts, extracts of marine, thermal and lake mud and phytoplankton extract." Algae extract, bacterial extracts, extracts of marine, thermal and lake mud and phytoplankton extract are not basic amino acids. It is thus improper to include algae extract, bacterial extracts, extracts of marine, thermal and lake mud and phytoplankton extract in the grouping for basic amino acid in the Markush group.

Appropriate correction is respectfully requested. The part of the claims that deal with algae extract, bacterial extracts, extracts of marine, thermal and lake mud and phytoplankton

extract as basic amino acids will not be addressed and the rejection below will deal with a composition for treating allergic reactions where the composition contains basic amino acids selected from the group consisting of “arginine...and salts thereof.”

Also, “cucurbitine” and “homarine” do not appear to be basic amino acids.

The amendment submitted on 12/04/04 appears not to have support in the disclosure as originally filed and applicants failed to point to the sections of the specification that supports the amendment.

***Claim Rejections - 35 USC § 103***

4. Claims 57 and 58 remain rejected under 35 U.S.C. 103(a) as being unpatentable over JP 404126057.

Applicants argue that the instant claims are not obvious over the JP reference does not teach the instant method because the JP prior art does not teach medical treatment whatsoever. Applicants argue that the method of the instant application has to do with “a method or treating warm-blooded animals to inhibit activation of mastocyte or degranulation of basophiles by administering to warm blooded animals in need thereof an amount of a composition comprising 3-95% by weight of sea water and 0.001 to 10% by weight of at least one basic amino acid selected from the group consisting of specific acids in amounts sufficient to inhibit activation of mastocytes and degranulation of the basophiles.” Applicants then cite Ex parte Hessel, 137 USPQ 384 to state that claims directed to a method of controlling and eradicating nematodes was patentable over a reference showing insecticidal or fungicidal activity and that applicants are treating

specific condition not taught by the prior art reference and that one skilled in the art would not use a soft drink for the method of treatment claims.

5. Applicants' arguments filed 07/16/04 have been fully considered but they are not persuasive.

To begin with, the claims recite "0.0001 to 10%" by weight and not 0.001 to 10% as stated in the remarks filed 07/16/04.

The soft drink of the prior art containing at least one basic amino acid and sea water is consumed by a mammal and would inherently treat the conditions recited.

The abstract of the JP reference discloses a composition comprising seawater, adequate amounts of water, saccharides, a fruit juice, proteins, an amino acid, vitamins, vegetable extracts, carbonic acid, a flavoring agent, a sweetener, lactic acid and lactic acid bacteria, honey, nicotinic acid, sodium glutamate, a sour agent, a thickener, a colorant, a stabilizer, an emulsifying agent, fiber, fats, ash, arginine, caffeine, preservative and caramel as presented in the last office action. Amino acids including the basic amino acids have amino groups/moieties. Also, salts of amino acids are obvious variants of amino acids.

Claims 57 and 58 are amended to include the amounts of sea water and amounts of the basic amino acid. Consultation of the translation of the JP reference shows that, the prior art discloses 3-5% of sea water in the soft drink and this amount meets the limitation of the lower limit of 3-95% by weight of sea water. However, the JP reference (translation), while disclosing that the soft drink contains sodium L-glutamate, arginine, caramel, lactic acid and stabilizer among other ingredients, is silent on the amount of the basic amino acids in the soft drink. The amounts of the basic amino acids recited in claims 57 and 58 in the amount of 0.0001% for the

lower limit appears to represent trace amounts. However, it is known that sea water contains amino acids and Chau et al. in ("The determination of amino acids in sea water," in the Deep-Sea Research, 1966, Vol. 13, pp. 1115-1124) which is a teaching reference added to show that sea water contains amino acid, discloses the kinds of amino acids found in sea water.

However, applicants' argument is directed to the assertion that the JP reference does not teach the instant method. It is respectfully noted that the instant method administers to a warm blooded animal a composition that is disclosed and administered to a subject as a soft drink in the prior art except for the trace amounts of the basic amino acid that is provided/supplied by the sea water as disclosed by the teaching reference. Thus both the prior art and the instant claims are administering a composition that has sea water as a component part of the composition. Thus while the instant invention may have recognized that administration of a composition containing sea water has an inhibitory effect on mastocyte activation or allergic reactions, the instant claims are not patentable over the prior art. In re Cruciferous Sprout Litigation, 64 USPQ2d 1202, N0. 02-1031, decided August 21, 2002 supports the premise of the Examiner's position. It is also noted that effective amount is any amount that is considered effective.

Regarding Ex parte Hessel, nematodes and insects and fungus are not the same. In the instant case a mammal such as human is warm blooded. In the ex parte Hessel decision, ex parte Santmyer was also cited in which an amine is used to control worms by treating soils with the amines while the prior art uses those amines to protect lumber from attack by beetles. Lumber and soil are not the same. In the present situation a composition containing sea water and trace amounts of basic amino acids is administered to warm blooded animals in both cases.

*Specification*

6. The disclosure is objected to because of the following informalities: The representation of “<<neurogenic>>” on page 3, paragraph 4, “”<<mucous>> and <<mastocytes of the conjunctive tissue>>” on page 10, under a) Introduction of the specification need to be explained as to what those stand for.

Appropriate correction is respectfully required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

